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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,186	09/21/2007	Rudolf Brenneisen	8588-US	3801

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EXAMINER	
HA, JULIE	

ART UNIT	PAPER NUMBER
1654	

NOTIFICATION DATE	DELIVERY MODE
02/09/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/580,186	BRENNEISEN ET AL.	
	Examiner	Art Unit	
	JULIE HA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) *1-9,33,36,37 and 41-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-32,34,35,38-40 and 45-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/22/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Responses to Election/Restriction filed on August 11, 2009 and November 02, 2009 is acknowledged. Claims 1-47 are pending in this application.

Restriction

1. Applicant's election with traverse of Group 3 in the reply filed on August 11, 2009 is acknowledged. The traversal is on the ground(s) that each of the independent claims is generally directed to a γ-glutamyl peptide, and γ-glutamyl peptide can be used in the preparation of a medicament or nutritional formulation. Applicant argues that the use of γ-glutamyl peptide is the single general inventive concept that is shared by the pending claims. Applicant further elects γ-L-glutamyl-S-(trans-l-propenyl)-L-cysteine sulfoxide as the γ-glutamyl peptide, skim milk powder as the calcium source, maltodextrins as the carbohydrate, omega-6 polyunsaturated fatty acid source as the fat source, soy bean derived protein as the nitrogen source, Vitamin A as the vitamin, potassium as the mineral, gum Arabic as the fiber, vegetable flavors as the flavor, and Allium cepa as the Allium with traverse. Applicant further elects γ-glutamyl-alkyl-cysteine sulfoxide as the γ-glutamyl-peptide, osteoporosis as the disease, calcium chloride as the calcium source, carbohydrate as the energy source, maltodextrins as the carbohydrate, vitamin D as the vitamin, with traverse on November 02, 2009. Applicant argues that there is no burden to search the additional components. Applicant argues that "the Patent Office needs to find only a single species or a single component in the case of the Markush group of

Claim 20 for the claim to be anticipated. The Patent Office does not need to find every possible species of each component."

2. This is not found persuasive because the special technical feature of Invention 3 is disclosed by Kuttan et al (Biochemistry, 1974). Kuttan et al teach isolation of γ-L-glutamyl-S-(trans-l-propenyl)-L-cysteine sulfoxide from sandal (*Santal album L*). The reference teaches powder form, and teaches that the γ-L-glutamyl-S-(trans-l-propenyl)-L-cysteine sulfoxide is in aqueous solutions, water. Water is nutritionally and pharmaceutically acceptable carrier, therefore, the special technical feature is known in the art. Therefore, there is lack of unity of invention. In regards to the species election, the species lack the same or corresponding special technical feature since the species do not share a core structure and have patentably independent and distinct structures, as described in the previous office action. As indicated at paragraph 10 of the restriction requirement mailed on October 22, 2009, **"Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 102(a) of the other species**."

3. The requirement is still deemed proper and is therefore made FINAL. There are inconsistencies between the elected species filed on August 11, 2009 and November 02, 2009. For example, Applicant elected skim milk powder as the calcium sources and vitamin A as the vitamin on the election filed on August 11, 2009. Applicant elected

calcium chloride as the calcium source and vitamin D as the vitamin on the election filed on November 02, 2009. For the purpose of this examination, the election of species filed on November 02, 2009 will be examined. Search was conducted on the elected species, and prior art was found. A prior art WO 98/50054 A1 teaches the other nonelected species. Therefore, election of species is hereby withdrawn. Claims 1-9, 33, 36-37 and 41-44 are withdrawn from further consideration, pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Claims 10-32, 34-35, 38-40 and 45-47 are examined on the merits in this office action.

Objection

4. Claims 34-35 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 34 is dependent of claim 30, which is drawn to "The γ-L-glutamyl-trans-S-l-propeyl-L-cystein sulfoxide". Claim 34 is drawn to "The process of claim 30." Claim 35 is dependent on claim 34. Since claim 30 is drawn to a composition, claims 34-35 do not further limit claim 30.

Rejection

35 U.S.C. 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 10, 23-24, 27 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Blatt et al (US Patent No. 6,270,803, issued 2001).

7. Blatt et al teach orally-administrable formulations for the controlled release of granulated garlic, comprising particles of granulated garlic coated with a film comprising a mixture of at least one water soluble polymer and at least one water insoluble polymer (see abstract). The reference teaches that powdered and granulated garlic are good sources of allicin, γ-glutamyl peptides and certain other bioactive compounds. Allicin and γ -glutamyl peptides have broad and significant biological and therapeutic activities (see column 1, lines 12-15). Since the reference teaches formulations comprising granulated garlic, and granulated garlic comprises allicin and γ -glutamyl peptides, this meets the limitation of claims 10, 23-24 and 27. Furthermore, since the reference teaches γ-glutamyl peptide of instant claims, the γ-glutamyl peptide of reference would inherently have all of the characteristics and functionalities of claimed γ-glutamyl peptide, meeting the limitation of claim 45. Therefore, the reference anticipates claims 10-12, 23-24, 27 and 45.

8. Claims 10-12, 22-26, 29-32, 34-35, 38 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuttan et al (Biochemistry, 1974, 13(21): 4394-4400, filed with IDS).

9. Kuttan et al teach isolation of γ-L-glutamyl-S-(trans-l-propenyl)-L-cysteine sulfoxide from sandal (*Santalum album L.*) (see abstract), meeting the limitation of claims 10-12. The reference teaches that the isolated peptide was compared with a sample of previously isolated peptide from onion (Allium cepa) (see abstract). The reference teaches that the powder form (colorless, granular crystals, see p. 4396, left column, 1st paragraph of Results), meeting the limitation of claim 23. The reference teaches that γ-L-glutamyl-S-(trans-l-propenyl)-L-cysteine sulfoxide is in aqueous solutions, water (see p. 4396, right column, "CD ABSORPTION"). Water is nutritionally acceptable carrier, therefore, meets the limitation of claims 10-12, 22-26. For the prosecution, claims 34-35 have been interpreted as product by process claims, since they depend on product claims 29-30. Claims 29-32 and 34-35 are drawn to product by process. The MPEP states the following: “[E]ven though product-by-process claims are limited by and defined by the process determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process...The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead

produced in-situ does not change the end product" (see MPEP 2113 [R-1]). Furthermore, since the reference teaches γ-glutamyl peptide of instant claims, the γ-glutamyl peptide of reference would inherently have all of the characteristics and functionalities of claimed γ-glutamyl peptide, meeting the limitation of claims 38 and 45. Therefore, the reference anticipates claims 10-12, 22-26, 29-32, 34-35, 38 and 45.

10. Claims 10-32, 34-35, 38-40, and 45-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Muhlbauer (WO 98/50054, filed with IDS).

11. Muhlbauer reference teaches a nutritional composition comprising all of the active components of instant claims (see throughout the reference, Claims 5-20), meeting the limitation of instant claims 10-32, 34-35, 38-40 and 45-47. The reference teaches that the nutritional or pharmaceutical compositions containing a plant extract or concentrate selected from the group consisting of allium, eruca, petroselinum and brassica extracts or concentrates (see abstract and p. 2, last paragraph). The reference teaches that the composition is useful for the treatment of diseases or conditions which are characterized by increased bone resorption, osteoporosis (see abstract). The reference teaches that the term allium refers to the genus allium and includes for example any member of the botanical species Allium cepa (onion), Allium ascalonium and so on, and indicates that the preferred extract is from Allium cepa (see p. 3, 2nd paragraph, see p. 4, 6th paragraph). The onion extracts and concentrates are prepared from the whole eatable part of the vegetable (see p. 3, 3rd paragraph). The reference teaches that the extract and concentrates of the above-mentioned plants or vegetables

may be in liquid form or in solid form such as in granulate or powder form (see p. 5, 1st paragraph), meeting the limitation of claims 22-23. The reference teaches that suitable methods of obtaining extracts of the above-mentioned plants or vegetables are known in the art…by extracting the fresh cut or dried plants or vegetables or the respective roots, fruits or seeds thereof for example with water or with one or more food grade solvents or with a mixture of water and one or more food grade solvents…ethanol (see p. 5, 3rd paragraph). Further, Example 4 at page 16, explicitly teaches ethanol/water extraction. As evidenced by instant specification, "the active constituent of allium responsible for the bone resorption inhibiting effect, may be found in a hydrophilic, ethanolic extract of allium such as Allium cepa. The active constituent having a potent inhibitory effect on bone resorption was identified as γ-glutamyl peptide, γ -glutamyl-alkyl cysteine sulfoxide or γ -glutamyl-alkenyl-cysteine sulfoxide, a γ-L-glutamyl-trans-S-1-propenyl-L-cysteine sulfoxide (see paragraph [0012] of instant specification). Therefore, the ethanolic extract of allium cepa of the reference would inherently comprise the γ-L-glutamyl-trans-S-1-propenyl-L-cysteine sulfoxide of the instant claims. Further the reference teaches that after the extraction step, the liquid phase is optionally concentrated or dried by evaporation or freeze drying (see p. 5, 3rd paragraph), meeting the limitation of instant claims 29-32 and 34-35. For the prosecution, claims 34-35 have been interpreted as product by process claims, since they depend on product claims 29-30. Please note, claims 29-32 and 34-35 recite a product by process claims. The MPEP states the following: "[E]ven though product-by-process claims are limited by and defined by the process determination of patentability is based on the product itself. The

patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process...The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product" (see MPEP 2113 [R-1]).

The reference teaches that the extract may be used in liquid form, particularly in aqueous form, or in solid form, granulate or powder form. If the extracts in liquid form, it has a solid contents of for example from 1 to 25% by weight, preferably from 2 to 20% by weight and most preferred from 2 to 15% by weight (see p. 6, 2nd paragraph). The reference teaches that the subject to be treated is an adult person a satisfactory inhibitory effect on bone resorption is, in general obtained with compositions formulated to allow a daily administration of 0.1 to 20 grams, preferably 0.2 to 15 grams and most preferred 0.4 to 10 grams of allium, petroselinum, brassica and/or eruca concentrate or extract (see p. 6, 2nd paragraph). The reference further teaches that suitable nutritional compositions comprising the plant/vegetable extracts comprise at least one (a) plant/vegetable extract or concentrate from allium, (b) a calcium source, and (c) at least one energy source selected from carbohydrate, fat and nitrogen sources, and Vitamin D (see p. 6, last paragraph, claim 5), meeting the limitation of instant claims 10-13, 38 and 45. Since the nutritional composition comprises the same active compound, this would inherently have the same functionality and characteristics of instant claims 38 and 45.

Furthermore, since the reference teaches the same nutritional/ pharmaceutical composition for the purpose of treating increased bone resorption, osteoporosis, the nutritional/ pharmaceutical composition would inherently have the same effective dose, meeting the limitation of claims 39-40 and 46-47. The reference teaches that from approximately 0.1 to 40%, preferably from approximately 3 to 25% of plant/vegetable extract or concentrate component (a) (see p. 6, last paragraph); calcium source such as calcium chloride or skim milk and the calcium source (b) is in one unit dosage from about 100 mg to 1000 mg, preferably 200 mg to 700 mg or from approximately 1 to 60 %, preferably from approximately 5 to 50% of calcium component (b) (see p. 7, 1st and 2nd paragraph); suitable carbohydrate sources include for example maltodextrins, starch, lactose, glucose (see p. 7, 3rd paragraph); suitable fat sources include omega-6 polyunsaturated fatty acid (see p. 7, 4th paragraph); suitable nitrogen sources such as soybean derived proteins (see p. 8, 4th paragraph), meeting the limitation of claims 14-17 and 19. The reference teaches that the nutritional composition comprise from approximately 0.1 % to 98.9%, preferably from approximately 1 to approximately 95% of energy source (p. 9, 1st paragraph), further meeting the limitation of claim 19. The reference teaches that the carbohydrate source provides for 30 to 70% of the total energy supply, the nitrogen source for 5 to 45 %, and the fat source for 0.1 to 15% of the total energy supply (see p. 9, 2nd paragraph), meeting the limitation of instant claim 18. Further, the reference teaches that the nutritional formulation may comprise other nutritionally acceptable components such as vitamins (see p. 10, 1st paragraph), meeting the limitation of instant claim 20. The reference teaches that the supplement

comprises energy sources in an amount supplying from 50 to 1500 kcal/day (see p. 11, 2nd paragraph, see claim 16), meeting the limitation of instant claim 21. The reference teaches that the nutritional formulation is formulated in any form suitable for enteral administration, in aqueous form or in powder or granulate form, whereby the powder or granulate is conveniently added to water prior to use (see p. 11, 1st and 2nd paragraphs), meeting the limitation of claims 24-26. Additionally, the reference teaches dragee, table, capsule, sachet or suppository compositions (see p. 12, 3rd paragraph, see claim 20), meeting the limitation of instant claims 27-28. Therefore, the reference anticipates instant claims 10-32, 34-35, 38-40 and 45-47.

Conclusion

12. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Julie Ha/
Examiner, Art Unit 1654